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THEME ARTICLE

A Medical Writer's Guide: Working on Clinical Research Manuscripts for Submission to Peer-Reviewed Medical Journals

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ABSTRACT

Prompt publication of clinical trial results in peer-reviewed journals is essential to advance clinical practice and improve patient outcomes. The involvement of professional medical writers (PMWs) in the preparation of these clinical research manuscripts can enhance their quality and shorten publication timelines. Research manuscript projects can be daunting, especially for early-career PMWs who could benefit from insights provided by experienced PMWs. In this guide, first I share my perspective on how PMWs contribute to such projects and the essential skills and competencies we should provide. Then, I describe my tactical approaches to initiating these projects, developing the first draft of a detailed outline or manuscript, and avoiding some common pitfalls that can undermine the quality of a manuscript. Finally, I share some tips for working with challenging personalities.

There are many types of biomedical research manuscripts (Figure 1).[1] Research manuscripts that report the results of clinical investigational studies are among the most impactful articles published in peer-reviewed biomedical journals. Prompt publication of clinical trial results is essential to facilitate discussion of their implications for clinical practice and any potential improvements in patient outcomes. However, because clinical investigators need to balance clinical, research, and other responsibilities, they usually have limited time to prepare manuscripts for journal submission. Their junior medical colleagues often have even less time and less training in writing scientific manuscripts. The involvement of professional medical writers (PMWs) in the preparation of research manuscripts can improve their quality and shorten publication timelines.[2-4] In this context, PMWs lay the groundwork for building a submission-ready manuscript like specialist nurses or physician assistants do for physicians treating patients.

For early-career PMWs, working on research manuscript projects can be a daunting challenge. In this guide, I share my perspective on the role of PMWs in such projects, our key functions and responsibilities, and tactics and tips that have helped me excel at these projects.

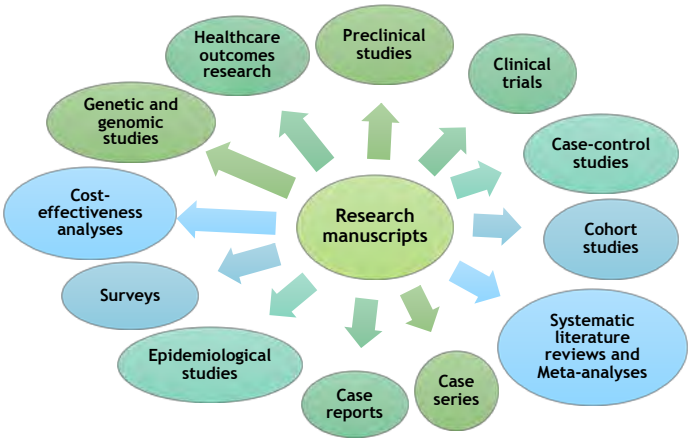

Figure 1. Types of biomedical research manuscripts.

HOW MEDICAL WRITERS CONTRIBUTE TO RESEARCH MANUSCRIPT PROJECTS

In collaboration with the lead clinical investigators/authors and under their guidance, PMWs can contribute to various aspects of manuscript preparation (Figure 2, next page). As a freelance PMW, I have sometimes been asked to prepare only a partial or complete first draft. Other times, I have supported research manuscript projects from conception and through various revisions, until readiness for journal submission. Occasionally, I have been tasked with revising the work of others for submission to a different journal.

The work of PMWs on research manuscript projects must reflect guidance provided by professional ethics,[5-8] standards for best practice,[9-13] applicable health research reporting guidelines,[14] and journal-specific instructions for authors (Figure 3, next page). In light of this guidance, my main goal as a PMW is to produce a succinct, clear, well-organized, and accurate draft document that reports the results of a study and the authors' interpretation while adhering to the guidelines for the target journal. By producing a high-quality, data-supported work, I maximize the chances that the

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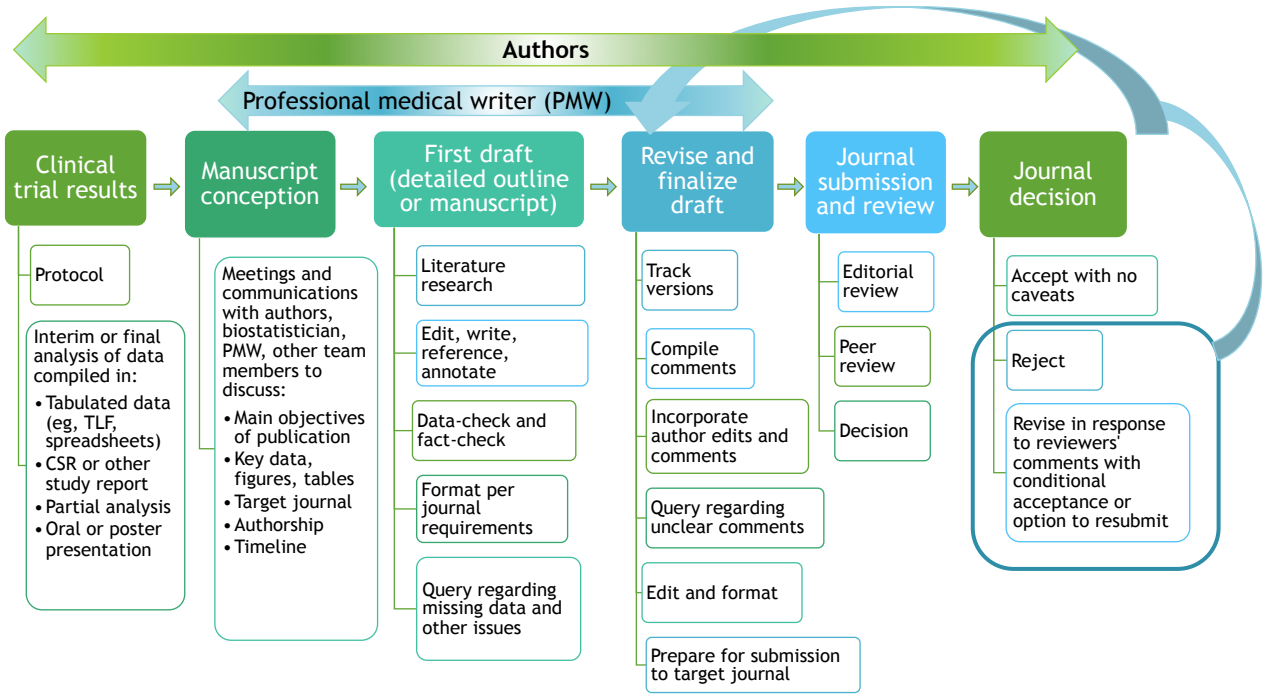

Figure 2. How a PMW might contribute to the preparation of a clinical trial research report for submission to a peer-reviewed journal.

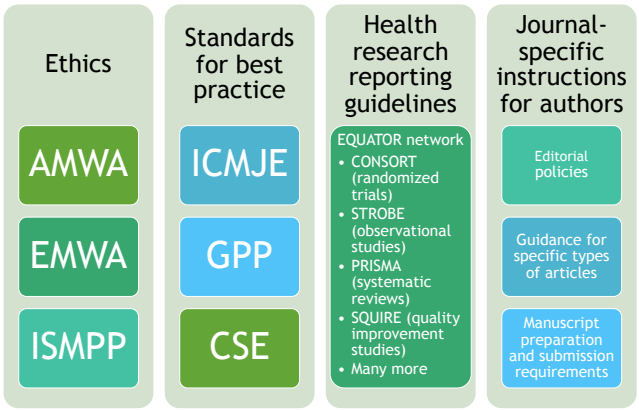

Figure 3. Key sources of guidance for PMWs working on research manuscripts. AMWA, American Medical Writers Association; CSE, Council of Science Editors; EMWA, European Medical Writers Association; GPP, Good Publication Practice; ICMJE, International Committee of Medical Journal Editors; ISMPP, International Society for Medical Publication Professionals; PMW, professional medical writer.

manuscript will be accepted for publication and minimize the work required of others (eg, authors, editors, other collaborators, colleagues).

As a PMW of a research manuscript, I am usually not considered an author because my contributions do not meet all 4 of the International Committee of Medical Journal Editors (ICMJE) criteria for authorship (Figure 4).[9] Per ICMJE standards, journal guidelines, and other best practices, manuscripts must acknowledge the contributions of PMWs and medical editors along with the source of funding for their work.

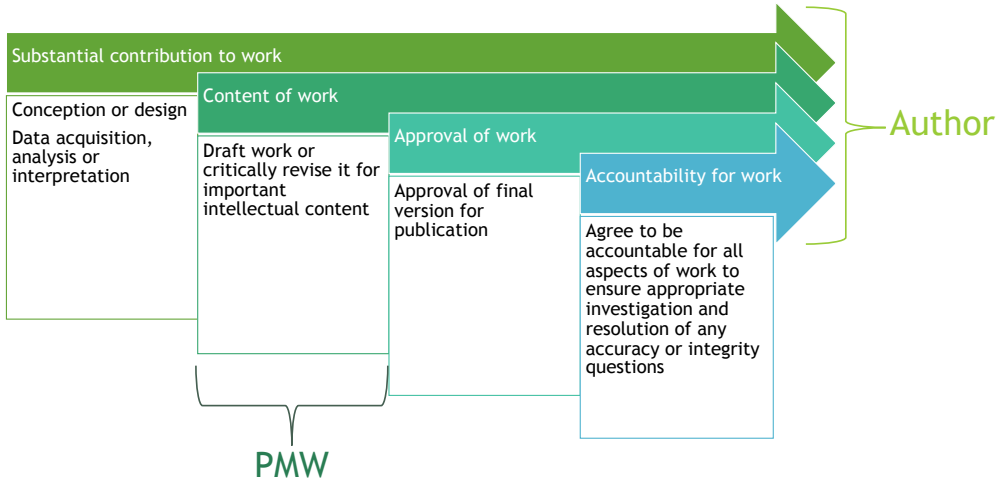

Figure 4. How ICMJE authorship criteria usually apply to PMWs working on research manuscripts.

ESSENTIAL SKILLS AND COMPETENCIES FOR WORKING ON RESEARCH MANUSCRIPTS

PMWs must have a variety of skills and high-level competencies (Figure 5). It is not a hobby that can be casually picked up—it's a profession. For example, being considered a good writer as an undergraduate, earning a doctorate in a life science field, doing postdoctoral research, and being an author of several nonclinical research manuscripts did not automatically make me a good medical writer. I was fortunate to be hired as an entry-level medical writer at a medical communication company. While there, I developed my medical writing and editing skills through AMWA workshops and seminars, diligent practice, reading good medical writing, and receiving constructive criticism and feedback from medical editors and other experienced colleagues. When I started my own freelance business, I continued to expand these skills by always striving to improve.

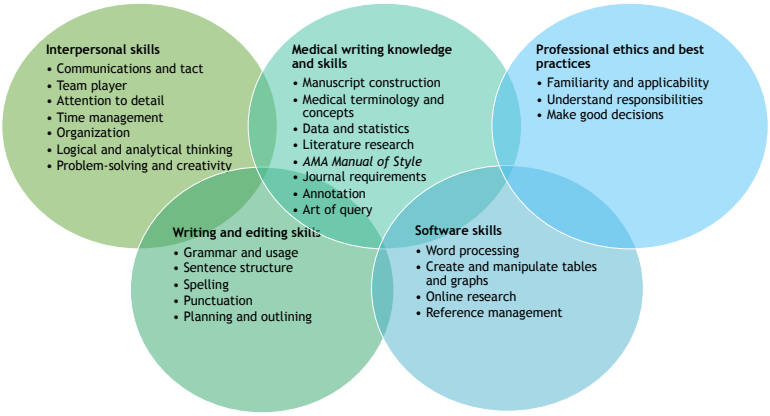

Figure 5. Essential knowledge and skills for medical writers working on research manuscript projects.

Mastering the craft of medical writing is key to successfully completing a research manuscript project. The *AMA Manual of Style*[1] is an important resource for PMWs who work on manuscripts for submission to American medical journals. Most of these journals base their style and format on the *AMA Manual*. When I work on a manuscript for submission to a peer-reviewed journal, I apply the *AMA Manual* guidance (for examples, see Table 1) along with guidance provided by the journal's

Table 1. Selected Recommendations for Good Medical Writing of Research Manuscripts Reporting Clinical Trial Results

Topic	Applicable Statements From *AMA Manual of Style* 11th Edition	My Recommendations
Active Voice Versus Passive Voice	"In general, authors should use the active voice, except in instances in which the actor is unknown or the interest focuses on what is acted on …"[1,a] "If the actor is mentioned in the sentence, the active voice is preferred over the passive voice."[1,a]	Use a judicious mixture of active voice and passive voice. Active voice makes the writing clearer and more concise. It also emphasizes the authors' ownership of their work. Too much passive voice makes the writing boring and verbose, causing the reader to lose interest.
Patient or *Participant* Instead of *Subject* or *Case*	"Some consider *subject* (as in study subject) to be impersonal, even derogatory, as if the person in the study were in a subservient role. Similarly, the use of *case* is dehumanizing when referring to a specific person."[1,b]	Use the term patient if the study *participant* is being treated for a medical condition. Use the term *participant* or *volunteer* if the study participant is healthy and/or is not being treated. Keep in mind that the study participants or their loved ones might read the publication. We must show respect for their personhood and contributions.
Sex and Gender	Use sex-neutral terms when applicable. For example:[1,c] • *Chair* or *chairperson* instead of *chairman* or *chairwoman* • *Layperson* instead of *layman* • *Humankind* instead of *mankind* "When reporting the sex of participants in a table, include both sexes, as identified in the study, regardless of the ratio. Do not use "white" and "male" as the default."[1,d]	Report data on sex and gender in an equitable, inclusive, and consistent manner. Don't report only the data for the majority group. When sex/gender is irrelevant, reword the sentence to use they as singular or plural. This is an evolving area; read on the topic,[15,16] attend an AMWA talk about it, and research the latest trends.
Race and Ethnicity	"… be sensitive to the designations that individuals or groups prefer. Be aware also that preferences may change and that individuals within a group may disagree about the most appropriate designation."[1,e]	Report data on race and ethnicity in an equitable, inclusive, and consistent manner. Don't report only the data for the majority group. Be as specific as possible when reporting data by race and ethnicity (eg, include definition of "other" category).
Terms for People With Conditions, Disorders, or Diseases	"Avoid labeling (and thus equating) people with their disabilities, or diseases (eg, the blind, schizophrenics, epileptics). Instead, put the person first."[1,f] "Avoid describing persons as victims or with other emotional terms that suggest helplessness."[1,f]	Some of my preferred phrasing: • *Patient with cancer* instead of *cancer patient* or *cancer victim* • *People with obesity* instead of *the obese* • *Persons (or people) with COVID-19* instead of *COVID-19 patients (or cases)* • *Older patients (or patients ≥ 65 years of age)* instead of *the elderly*

[a]Page 431, [b]page 513, [c]pages 543-544, [d]page 544, [e]page 546, [f]page 547.

manuscript preparation instructions. Doing so improves the consistency and clarity of my work and helps me educate other collaborators (eg, authors, clients, colleagues) on best practices in medical writing.

HOW TO GET STARTED ON A CLINICAL RESEARCH MANUSCRIPT PROJECT

As I work on these manuscripts, I am especially cognizant of the second principle from the AMWA code of ethics, which states that "Medical communicators should apply objectivity, scientific accuracy and rigor, and fair balance while conveying pertinent information in all media."[5] As PMWs, we must keep this principle at the forefront when we synthesize information and data from various sources (Figure 6) to produce cogent and accurate drafts for authors to develop.

Once I receive a research manuscript assignment, I take several steps to ensure that I start the project efficiently (Table 2). First, I review and organize the provided assignment document(s), background information, and other materials. As a freelancer who is usually not bound to a company's internal processes, I have developed my own system of 5 main electronic folders (named Background, Communications, Paperwork, References, Text), each labeled with a client and project code. I make sure that I understand the project specifications, the team's roles and

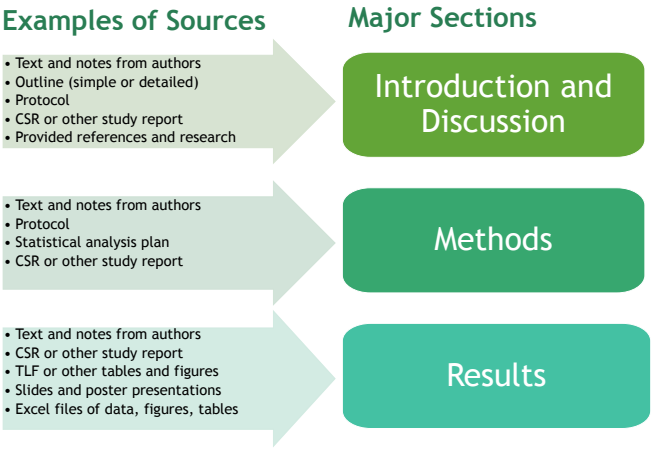

Figure 6. Examples of information and data sources for the major sections of a clinical research manuscript. Notes from authors can come from meetings, emails, and phone calls. CSR, clinical study report; TLF, Tables, Listings, and Figures.

Table 2. Key Steps and Tips for Starting a Manuscript Project for Submission to a Medical Journal

Step	Tips
1. Study and organize materials, and keep them organized.	• Organize project materials into standardized electronic folders. • Keep emails and notes of kick-off and follow-up phone conversations and live/online meetings (start and maintain a paper trail to document everything).

2. Determine what else is needed, keep notes on the project, and proactively communicate issues.	• Take notes regarding project-related questions and issues that arise.
	  ○ If issues can't be resolved by digging deeper in material, send queries via emails to a key contact.
	  ○ Keep track of queries and responses (eg, save emails in project subfolder).

3. Review author manuscript preparation instructions for target journal.	• Find examples of recent articles from journal.
	• Take notes on requirements and stylistic preferences:
	  ○ Word counts for abstract and main text.
	  ○ Limits for numbers of tables, figures, and references.
	  ○ Types of headings.
	  ○ Data format (eg, *P* values, significant digits).

4. Set up Word manuscript file.	• Follow the author manuscript guidelines for the target journal. • Modify the heading styles to outline and organize your draft. • Include a statement acknowledging contributions as a medical writer/editor and the source of funding for this work. • Use the Quick Access toolbar, keyboard shortcuts, Navigation Pane, and split screen option (View panel) to work efficiently.
5. Set up reference management library (eg, EndNote).	• Import citations from PubMed, other databases, and journal websites. • If needed, correct EndNote style to match current format used by journal.
6. Use easy and consistent naming formats for reference PDFs.	• My preference: First author's last name, journal abbreviation, year of publication (eg, Smith et al J Clin Oncol 2023) • Don't name files by their title (it's too long, and that's not how papers are cited) but do consider including a short phrase summarizing the title (eg, Smith et al J Clin Oncol 2023 [phase 3 drugX melanoma]).
7. Use a file naming system that promotes version control	• Name files in a consistent manner (eg, "smith phase2 ms d1.0"). • Have reviewers add initials when they send in their comments or rename the file yourself when you receive it (eg, "smith phase2 ms d1.0_MN").

PDF, portable document format.

responsibilities, the format for required deliverable (eg, outline, manuscript), and the timeline. When I work with a new group, I also need to confirm the lines of communication (eg, who will answer queries, who will provide portable document format (PDF) files for reference articles).

Second, I identify what else I need to start the project and decide on my next steps (eg, what questions to ask; what to research). Typically, the initial questions I need answered are:

- What sources of materials (eg, protocol, study report, key references) do I have to write and/or revise the draft?
- What is the target journal?
- What is the deadline for my first deliverable?
- Does the client want me to highlight sources and annotate the first draft? If yes, do they require a specific format?
- Which, if any, reference management software may I use?

Third, I study the journal's manuscript preparation instructions. To help structure and format the manuscript, I find 2 or 3 studies published in the target journal that are similar to the one that I am working on. I also try to find a few recent publications by the lead author(s) to get a general idea of their writing style.

Fourth, I set up the Word document. Unless a client requires me to use their template, I structure my Word manuscript to comply with the manuscript preparation instructions. I like to modify the style headings to help me outline and navigate the draft.

Fifth, I set up a reference management library for the project. I use EndNote. Other options include Mendeley and Zotero. A reference management software program is an essential time-saving tool for PMWs to manage references, create citations, and generate reference lists that conform to the target journal style.

Sixth, I use a consistent naming format for my reference PDFs so that I can easily access the correct reference as I develop a draft outline or manuscript. I used to print reference articles and other key sources, but I no longer do that. I work from the PDFs, keeping them side by side with my draft and highlighting and annotating as I go.

Seventh, I use a simple file naming system that promotes version control to minimize confusion during reviews. Of course, sometimes the lead author or client renames files using their own system. I stick with what they decide and keep detailed notes to keep track of versions and author responses.

HOW TO DEVELOP THE FIRST DRAFT OF A CLINICAL RESEARCH MANUSCRIPT

Similar to the approach recommended by other PMWs,[17] I start by drafting the Methods and/or Results, which are the most straightforward sections of a typical clinical research manuscript (Figure 7). This approach helps me familiarize myself with the study and avoid writer's block. Sometimes, perhaps because a section is tedious, I alternate working on different sections. Clinical trials tend to have similarly organized Methods section, unlike in vivo and in vitro experimental studies which have varied methodologies even within the same research area.

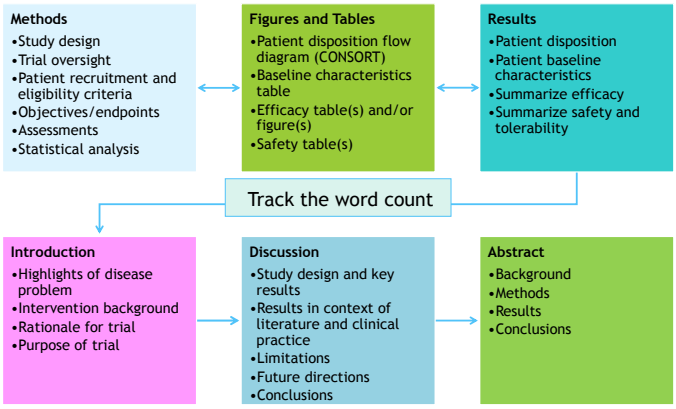

Figure 7. Sequential approach to building a research manuscript reporting clinical trial results.

After I have drafted the Methods and Results sections, I work on the Introduction and sketch out a discussion for the authors to modify and expand. The abstract is usually the last section I work on because I tend to build it by cutting and pasting key sentences from the main sections and then editing the text to fit the required word count. Once, a lead author asked that I start with the abstract to help him organize his thoughts at the onset of the manuscript. Luckily, I only had to update and edit an abstract that the authors had presented at a conference.

As I research and write the first draft of a detailed outline or manuscript, I highlight references and annotate corresponding PDFs (Figure 8). In comment boxes or within brackets in the text, I include notes and queries regarding any potential issues (eg, missing or unclear methods, inconsistent use of terms) (Figure 9). I also compile small batches of queries that require prompt attention because they impact how I proceed in my work and email them. It's important to resolve issues sooner rather than later. I absolutely do not want to submit a draft peppered with queries that should have already been resolved.

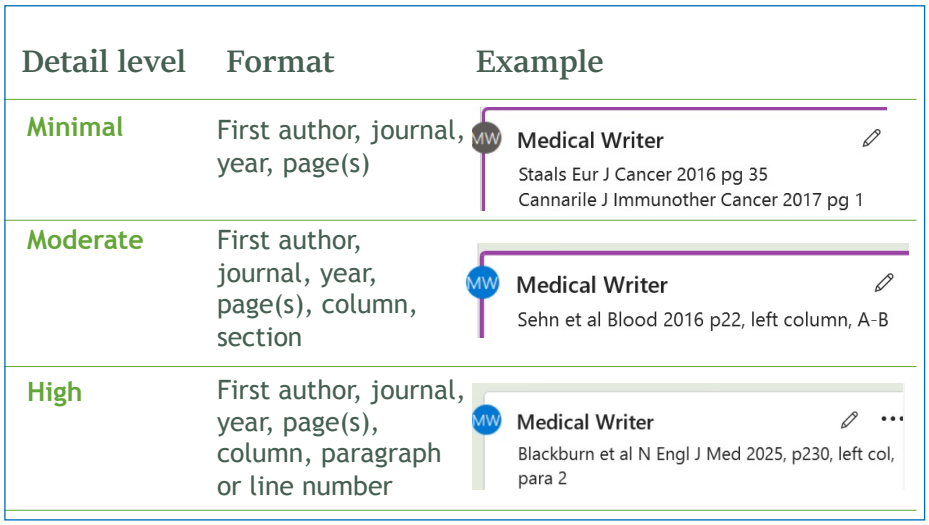

Figure 8. Examples of reference annotation formats.

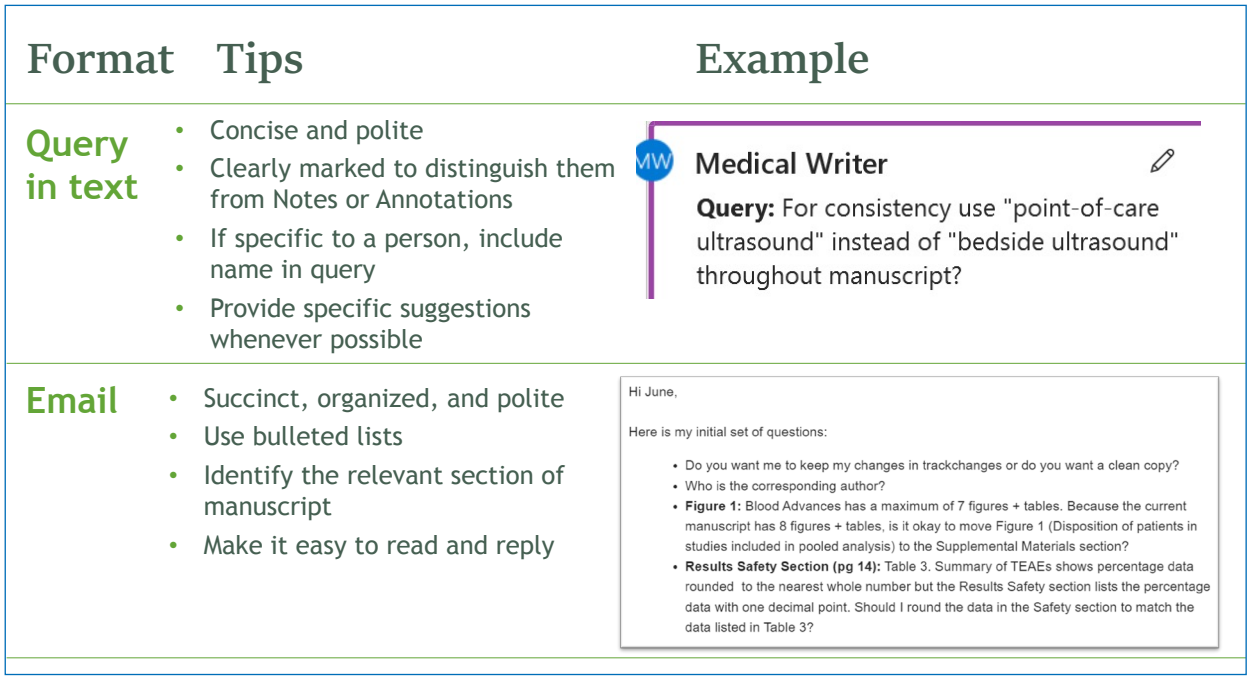

Figure 9. Tips and examples of in-text and email queries.

Throughout this work, I keep track of the word count (which for some journals can be quite stingy). Before I send any draft for review, I make sure to update the word counts for both the main text and the abstract. One of the tasks we have as PMWs is to help the authors comply with the word count requirements. This can be challenging during the draft revision process. When authors exceed the word count limit, I suggest edits in track changes to retain the meaning while reducing verbiage. Sometimes, I suggest that they move certain sections to an online supplement.

HOW TO AVOID COMMON PITFALLS

Common pitfalls of writing research manuscripts include accidentally plagiarizing published information and/or repurposing unpublished content; perpetuating inaccurate content; inserting erroneous data; creating a disorganized, inconsistent manuscript structure; and introducing typos, spelling mistakes, and poor grammar (Figure 10). Most of these errors are unintentional and are caused by taking shortcuts. I employ several tactics to avoid these pitfalls. If medical editors are on the project team, they will also check for these issues, but they might not be involved until later, and we should give them and the authors a well-written and organized draft to work on.

Cite and Paraphrase Content

Because plagiarism is unethical and infringes on intellectual property rights, PMWs should know how to paraphrase

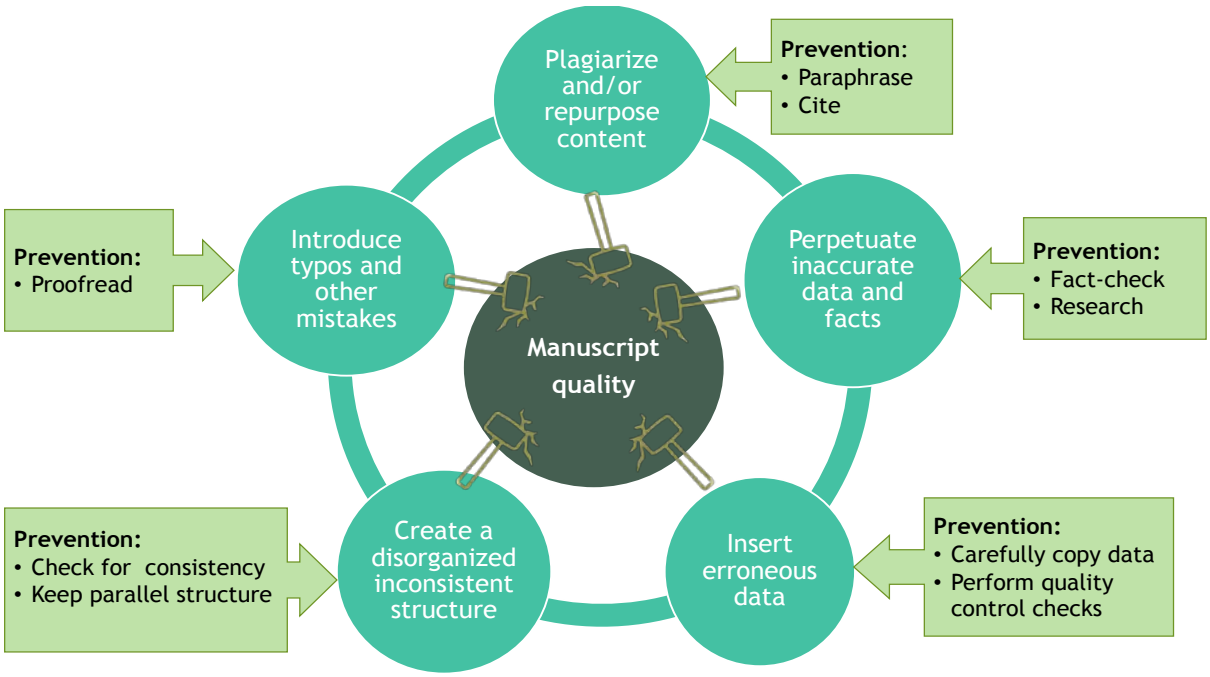

Figure 10. Common pitfalls and how to avoid them.

content and properly cite its sources. We should not succumb to the temptation of copying text from study protocols, clinical study reports (CSRs), and other unpublished documents. The writing style of such documents is often unsuitable for a journal article because it may be passive, formulaic, and verbose. It's better to paraphrase the material, pay attention to active and passive voice, and avoid using archaic terms like *subject* and *Caucasian*. I am also cautious about copying whole or parts of tables across files because disruptive formatting codes might transfer to the manuscript.

I would not use any content generated by an artificial intelligence program like ChatGPT. Several leading journals have published editorials discussing this controversial, still evolving technology and limiting or prohibiting its use in manuscripts submitted for publication.[18-21]

Verify Data and Facts

Another common pitfall in writing clinical research manuscripts is incorporating data and information cited in other documents (eg, protocols, CSRs, published articles) without factchecking the accuracy of each citation. I check the cited reference (often using the PDF search field to quickly find specific numbers or terms) to determine if it does indeed provide the information. Also, when the cited information is older than 1 to 2 years (depending on the field's pace of research), I do literature searches to identify more recently published sources. This is especially important for rapidly advancing fields like oncology in which, for example, the American Cancer Society publishes new statistics every year.

Even when not required by project specifications, I highlight references and annotate the detailed outline or first draft of a manuscript to keep a record of the sources of any included information and data. This documentation step does not take long, and it saves time and headache during the review/revision process in addressing questions regarding data accuracy, conflicting information, and other issues that might be raised by authors and other project participants.

I have noticed, when factchecking others' work, that some writers cite a published research manuscript as the source of information referred to in the Introduction or Discussion sections of the cited publication. This is a misleading use of a citation. For example, the Introduction section of a hypothetical phase 2 study by Smith et al on a new adjuvant drug for people with resectable pancreatic cancer mentions a range of reported median progression-free survival (PFS), citing 3 sources. Instead of taking the shortcut of inaccurately citing the Smith et al study in my manuscript, I would cite the primary sources for the PFS data or a reputable review. I would cite the Smith et al paper if I were discussing the results or conclusions of their study.

Avoid Inserting Numerical Errors

The compilation of data in tables and figures is one of most tedious tasks of a research manuscript project. It's challenging to keep track of and accurately copy numbers from large tables that were prepared for CSRs, Tables, Listings and Figures (TLFs), and other study reports. These are the steps I take to avoid losing track as I copy numbers:

- Place documents next to each other on a large screen.

- Enlarge source and recipient documents.
- Copy (cut/paste or retype) and round (if necessary) small batches of numbers at one time.
- After copying the numbers, highlight the data in the source document (to mark my place).
- Every 2 to 3 rows of copied numbers, backtrack and double-check the values to correct any typos.

The data in tables from CSRs, LTFs, and other statistical/mathematical outputs can be difficult to read because of the multiple digits to the right of the decimal (eg, 45.567% vs 45.6% or 46%). Often these digits are not scientifically significant, especially when they were generated to calculate percentages or mean/medians. As noted in the 11th edition of the *AMA Manual of Style*[1(p1010)], "When numbers are expressed in scientific and biomedical articles, they should reflect the degree of accuracy of the original measurement. Numbers obtained from mathematical calculations should be rounded to reflect the original degree of precision." The *AMA Manual* has a helpful section summarizing rounding rules.[1(p1011)] In addition to being scientifically accurate, rounded numbers are easier to read. However, before doing any rounding, it's important to verify with the authors how many significant digits they would like to use throughout their manuscript.

Create an Organized Consistent Manuscript

To create a well-organized and easy to read manuscript, PMWs must ensure the consistent use of terms, abbreviations, and data across the different sections of the manuscript (ie, abstract, main text, tables, figures, online materials). For example, the definition of an outcome measure described in the Methods and Results sections should match the definition used in a table. For numerical data, inconsistencies might especially occur whereby numbers are rounded in one section of the manuscript (eg, the Results text) but not in another (eg, a table, figure, or abstract). I use the Word Split screen option (Window submenu in the View bar) to help me verify that numerical data are reported in the same way across sections.

We should also use parallel structure in subheadings, paragraphs, and sentences that are discussing similar information. For example, the presentation of information in the Methods section should match the sequence and content of data discussed in the Results section.

Although some of these tactics may appear subtle, together they improve manuscript clarity and maintain reader's interest.

Proofread Your Drafts

As I work on a draft in Word, I turn on the Spelling and Grammar checker under the Proofing submenu of the Review tab. Despite this and careful writing, errors slip through. Thus, even if other people will review my work, I proofread it before sending any draft to the next step in the process. The point of proofreading is to catch and correct any mechanical errors, not to second-guess myself and rewrite.

It's challenging to proofread your own work because when you are immersed in writing a draft, your eyes tend to skim over words they have seen repeatedly, allowing errors to become invisible. To reset and refresh my eyes and brain after I finish a draft, I wait for several hours or, preferably, until the next morning before proofreading it.

I proofread on screen, zooming in to enlarge text 15% to 25% of my normal writing mode. Early in my writing career, I proofread printed drafts. I switched to working onscreen years ago because it works well for me and reduces paper waste. Other tips for proofreading onscreen include changing the background color, reading text aloud, and pointing at words as you read them. An interesting tactic Hope Lafferty, ELS, spoke about during her excellent AMWA 2022 Annual Conference education session entitled "Editing Your Own Work (After You've Read it 1,000 Times)" is to read text backwards, word by word or sentence by sentence.

TIPS FOR WORKING WITH CHALLENGING PERSONALITIES

Some authors and clients are easy to work with in a collaborative manner. Others might pose challenges. For example, they could be unresponsive, set in their ways, condescending, overly demanding, and inexperienced. Regardless, as PMWs we have to remember that the authors have the final say and responsibility for the content of their manuscript. We can offer suggestions and provide education, but all final decisions are theirs.

Patience and tact are essential for working with challenging individuals. For example, when I must respond to an irritating email, I draft a response and then step away from it for at least several hours before editing (usually to tone it down) and clicking send. Sometimes it might help to discuss the matter with a trusted colleague before further communicating with the difficult person.

During a project, I routinely keep all my emails in an organized fashion so that I can verify prior responses (keeping that paper trail documentation mentioned earlier). This is especially helpful when someone tells me to do one thing one week and something completely different a week later, doesn't respond to several polite emails asking for clarification or further instructions, or demands their draft earlier than agreed.

Other tactics for working with different personalities include:

- Be clear, concise, and tactful in all forms of communication (ie, email, queries in the drafts, voicemail).
- Suggest concrete solutions for issues regarding their writing—for example, instead of saying that text is unclear, I reword it into what I think it means and ask the authors if my edited version is correct.
- Use information from the *AMA Manual of Style*, journal author guidelines, and examples from articles published in the same journal or in more prestigious journals to educate about formatting and style decisions you implemented in a manuscript—for example, sometimes authors spend their valuable manuscript-review time to change "ie or eg" to "i.e. or e.g." They don't understand that I purposely used the unpunctuated abbreviations to follow the journal style (even though I noted on the first page that the manuscript is formatted per a specific journal). In these cases, I don't accept the author changes and explain my rationale, citing the appropriate style manual or manuscript preparation instructions.
- Try alternative ways of communication—some people who don't respond to emails might be reachable through a phone call or by first speaking with their administrative assistant or another member of the project team. Online meetings to share the screen and do edits live might work well for authors who never find the time to review drafts and send their comments via track changes.

FINAL WORDS

Being a PMW is rewarding and humbling. We should take pride in the ways we contribute to the clear and timely publication of research findings. It is gratifying to hear from authors how much they appreciate our work. However, we also have to accept feedback and corrections from editors, authors, and other stakeholders involved in the project. When we make mistakes, we should take responsibility, apologize, and learn. These actions help us grow as professionals and maintain good working relationships with authors, clients, supervisors, and colleagues. Regardless of whether a PMW works on research manuscripts or other types of projects, practice and ongoing learning are critical for success. To keep up with progress in our profession and in the therapeutic areas we work on, PMWs must continue to broaden our knowledge base and skill sets throughout our careers.

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